AUG 15 2012

Section 5: 510(k) Summary

1. Preparation Date: August 31, 2011

2. Submitted by: Altomec Endoscopy Inc
3310 Miller Road
Kalamazoo, MI 49001
Owner/Operator #: N/A – Not yet marketing the device
Small Business SBD118566

Contact Person/Prepared by:

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510(k) Submitter
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3. Device Identification:

Trade Name: Altomec Arthroscope
Common Name: Arthroscope
Classification Name: Arthroscope (21 CFR 888.1100; Product Code HRX)

4. Predicate Device: Stryker Arthroscope (K093677)

5. Device Description:

Altomec Arthroscopes are Non-deflectable rigid endoscopic devices, introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. The Altomec Rigid Arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. Lens along the rod relay the image. At the proximal end, a proximal coupling lens relays the image to a CCD (Camera). The Altomec Arthroscope has 140mm working length with an outside diameter of 4.0mm. The inner or optical tube that holds the optical system has a diameter of 3.25mm. The Altomec Arthroscope has a 105 degree field of view and 30 degree direction of view. The direction of view enables viewing of different parts.

Operating site is magnified two to five times of its actual size, depending on the distance between the tip of the endoscope and the object that is inspected. Magnified image is viewed on a monitor by connecting device's eyepiece to a video coupler of a camera monitor system. Image size on the monitor also depends on the type of video coupler used with camera system. Image can be recorded in a variety of formats depending on the camera system used.

Light is transmitted through glass fibers running between inner and outer tubes from distal end to the light post. Light transmission is achieved by connecting one end of a light cord to a light source and other end to the light post of the device. Device has no working channel. Sheaths with locking mechanism identical to predicate device, are used for irrigation.

6. Intended Use:

Arthroscopes are rigid endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy.
Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

7. Comparison to Predicate:

a) Technical

	Proposed Device	*Predicate Device*		
Device	**Altomec Arthroscope*	*Stryker Arthroscope*		

	Technological	Characteristics (Design)	Equivalence	Impact on Safety and Effectiveness
Field of View (FOV)	105	105	Same	N/A
Degrees Direction of View Degrees	30	30	Same	N/A
Outer Diameter	4mm	4mm	Same	N/A
Working Length	140mm	140mm	Same	N/A
Single use Or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	Storz and Olympus	Same	N/A

Technological Characteristics: The Altomec Arthroscopes are substantially equivalent in construction and materials to the predicate Stryker Arthroscopes.

b) Materials

	Proposed Device	*Predicate*
Parts/materials	**Altomec Arthroscope*	*Stryker Arthroscope*
Optical system	High quality optical glass	High quality optical glass
Outer tube	Medical grade Stainless Steel	Medical grade Stainless Steel
Inner (optical) tube	Medical grade Stainless Steel	Medical grade Stainless Steel
Spacers	Medical grade Stainless Steel	Medical grade Stainless Steel
Fiber Optic bundle(Light fibers)	Glass	Glass
Light cone	Glass	Glass
Recessed cover glass (window)	Soldered glass made from sapphires	N/A
Eyepiece	Ultem®(Polyetherimide)	N/A
Mechanical parts: Body, Light post, fiber guide and Ocular holder.	Machined on CNC/lathes using medical grade stainless steel	Machined on CNC/lathes using medical grade stainless steel
Adhesive	EPO-TEK®353ND (technical data sheet attached): Used for potting fiber optic bundle, light cone and fiber guide	N/A
Finished Silver Solder: Part Number SBSK. Composition 3.4-3.8% Silver, Remainder Tin.	Used for soldering Soldered Glass made from Sapphires.	N/A

8. Similarities/ Differences of the proposed device when compared to the predicate:

Performance Testing: The patient contacting materials are identical to the materials used in the predicated device (Stryker Arthroscope). The Altomec Arthroscopes met all specified design and performance requirements.

Predicate Devices: The Altomec Arthroscopes are substantially equivalent in terms of safety and effectiveness to the currently marketed device, Stryker Arthroscopes.

Substantial Equivalence: The technological differences between the Altomec Arthroscope and Stryker Arthroscopes do not raise new questions of safety or effectiveness. Therefore the Altomec Arthroscopes are substantially equivalent to the previously cleared Stryker Arthroscope. Refer to Section 7.0 for a detailed comparison.
The data within this submission demonstrates that there are no significant differences between the application device and the predicate, indicating that the application device is safe, effective and substantially equivalent for marketing in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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AUG 15 2012

Re: K112548
Trade/Device Name: Altomec Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: August 9, 2012
Received: August 9, 2012

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FDA U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Indications for Use Statement

510(k) Number (if known): K112548

Device Name: Arthroscope

Indications for Use:

Intended Use: Arthroscopes are rigid endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112548